DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 4, 2015

CreoDent Prosthetics, Ltd.
Mr. Calvin Shim
Managing Director
29 West 30th Street, 11th Floor
New York, New York 10001

Re: K150012
Trade/Device Name: CreoDent Solidex® Customized Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 4, 2015
Received: May 5, 2015

Dear Mr. Shim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K150012

Device Name: CreoDent Solidex® Customized Abutment

Indication for Use:

The CreoDent Solidex® Customized Abutment is intended for use with an endosseous implant to support a prosthetic device in patients who are partially or completely endentulous. The device can be used for single or multiple-unit restorations. The prosthesis can be cemented or screw retained to the abutment. An abutment screw is used to secure the abutment to the endosseous implant.

The CreoDent Solidex® Customized Abutment is compatible with the following:

- Biomet 3i Osseotite Certain Dental Implants 3.25mm, 4.0mm, 5.0mm, 6.0mm
- Straumann Bone Level Implants 3.3mm, 4.1mm, 4.8mm

Prescription Use___X____ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

CreoDent Prosthetics, Ltd.
Solidex® Customized Abutment

Submitter Information

Company Name: CreoDent Prosthetics, Ltd.
Company Address: 29 West 30th Street, 11th Floor
New York, New York 10001
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Contact Person: Calvin Shim
(212) 302-3860
Date Summary Prepared: June 4, 2015

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: CreoDent Solidex® Customized Abutment
Common Name: Endosseous Dental Implant Abutment
21 CFR 872.3630
Product Code: NHA
Classification Panel: Dental Products Panel
Reviewing Branch: Dental Devices Branch

INDICATIONS FOR USE

The CreoDent Solidex® Customized Abutment is intended for use with an endosseous implant to support a prosthetic device in patients who are partially or completely endentulous. The device can be used for single or multiple-unit restorations. The prosthesis can be cemented or screw retained to the abutment. An abutment screw is used to secure the abutment to the endosseous implant.

The CreoDent Solidex® Customized Abutment is compatible with the following:

- Biomet 3i Osseotite Certain Dental Implants 3.25mm, 4.0mm, 5.0mm, 6.0mm..
- Straumann Bone Level implants 3.3mm, 4.1mm, 4.8mm

DEVICE DESCRIPTION

The Solidex® Customized Abutment is Ti-6A1-4V Eli titanium alloy meets ASTM F-136 Standard and Screw is CP TI Gr4 meets ASTM F67 and is designed to be screw retained for use with endosseous dental implants to provide support for a prosthetic restoration. These abutments are indicated for cement or screw retained restorations. Solidex® Customized Abutments are compatibe with:

- Biomet 3i Osseotite Certain 3.25mm, 4.0mm, 5.0mm, 6.0mm diameter implants K063341
- Straumann Bone Level implants 3.3mm, 4.1mm, 4.8mm K083550 K121131

The design of subject device is customized to the requirements of each patient as may be specified by the prescribing dentist. Customization is limited by the minimum and maximum dimensions for wall thickness, diameter, height, collar height and angulation.

EQUIVALENCE TO MARKETED DEVICE

The **CreoDent Solidex® Customized Abutments** are substantially equivalent in intended use, material, design and performance to:

- Primary Predicate
    - Creodent Solidex Customlized Abutments (K113738)
- Reference Predicates
    - Biomet 3i Encode Patient Specific Dental Abutments (K101608)
    - Straumann Cares Titanium Abutments (K082764)
    - 3i Osseotite Certain Dental Implants K063341
    - Modified Dental Implant K083550
    - Straumann Bone Level Ø4.1mm and Ø 4.8mm Regular Connection (RC) Roxolid Dental Implants K121131

Conclusion:

The **Creodent Solidex® Customized Abutments** are substantially equivalent to the identified predicate products noted in this 510K Summary.

Table #1 Legally marketed predicate device (Abutment) to which equivalence is claimed:

Technological Characteristics	**CreoDent Solidex® Customized Abutment and Abutment Screw**	**Primary Predicate Device for claimed equivalence: Creodent Solidex Customized Abutment (K113738)**
Material	Abutment is Ti-6A1-4V Eli titanium alloy meets ASTM F-136 Standard. It is a higher grade material with more tensile strength. The Screw is CP TI Gr4 meets ASTM F67 Standard.	-Abutment and Screw: are CP Ti Gr4 and meets ASTM F67 standard. The Screw is exactly the same titanium alloy but the abutment is a lower grade(less tensile strength) titanium alloy compared to Ti-6A1-4V ASTM F-136 standard.
Performance Characteristics	Allows the prosthesis to be cemented or screw retained to the abutment. The abutment screw is designed to secure the abutment to the endosseous implant.	Allows the prosthesis to be cemented or screw retained to the abutment. The abutment screw is designed to secure the abutment to the endosseous implant.
Indications for Use	The CreoDent Solidex® Customized Abutment is intended for use with an endosseous implant to support a prosthetic device in patients who are partially or completely edentulous. The device can be used for single or multiple-unit restorations. The prosthesis can be cemented or screw retained to the abutment. An abutment screw is used to secure the abutment to the endosseous implant. The CreoDent Solidex® Customized Abutment is compatible with the following: • Biomet 3i Osseotite Certain Dental Implants 3.25mm, 4mm, 5mm, 6mm • Straumann Bone Level implants 3.3mm, 4.1mm, 4.8mm	The CreoDent Solidex® Customized Abutment is intended for use with an endosseous implant to support a prosthetic device in patients who are partially or completely endentulous. The device can be used for single or multiple-unit restorations. The prosthesis can be cemented or screw retained to the abutment. An abutment screw is used to secure the abutment to the endosseous implant. The CreoDent Solidex® Customized Abutment is compatible with the following: Nobel Replace™ TiUnite Endosseous 3.5mm (NP), 4.3mm (RP), and 5.0mm (WP) diameter implants. Nobel Active™ Internal Connection 3.5mm (NP) and 4.3mm (RP) diameter implants. Zimmer Screw-Vent 3.7mm, 4.7mm; Zimmer Tapered Screw-Vent 3.7mm (NP), 4.7mm (RP) and 6.0mm diameter implants.
Dimensions and Angulations	Creodent Solidex Customized Abutment sizes for Biomet 3i Osseotite Certain 3.25mm, 4.0mm, 5.0mm and 6.0mm diameter implants. Straumann Bone Level implants 3.3mm, 4.1mm, 4.8mm Angles not to exceed up to 20 degrees from	Abutment sizes for Nobel Replace™ TiUnite Endosseous 3.5mm (NP), 4.3mm (RP), and 5.0mm (WP) diameter implants. Nobel Active™ Internal Connection 3.5mm (NP) and 4.3mm (RP) diameter implants. Zimmer Screw-Vent 3.7mm, 4.7mm; Zimmer Tapered Screw-Vent 3.7mm (NP), 4.7mm (RP) and 6.0mm

	the implant axis.	diameter implants. Angles not to exceed up to 20 degrees from the implant axis.

Non-clinical Testing Data: Static/Fatigue testing was conducted in accordance with ISO 14801:2007E Dentistry-Implants-Dynamic fatigue test for endosseous dental implants with the worst case scenario for the Solidex® Customized Abutment connection platform. Reverse engineering dimensional analysis using compatible implant fixtures and sterilization validation according to ISO 17665-1 was performed. These results demonstrated that the Solidex® customized Abutment have sufficient mechanical strength for their intended clinical application and are compatible with the Biomet 3i Osseotite Certain and Straumann Bone level Dental implant system for which they are intended.

Substantial Equivalence discussion: The difference between the subject device and the Primary predicate is the compatible implant bodies. This difference is mitigated by fatigue testing, reverse engineering dimensional analysis, and identification of reference predicate for compatible implant bodies. The difference between the subject device and the primary predicate abutment is the titanium grade. The subject device is a higher grade titanium alloy that exhibits higher tensile strength. The difference is mitigated by fatigue testing. The screw material is exactly the same.

Table #2 Legally marketed predicate device (Abutment) to which equivalence is claimed:

Technological Characteristics	**CreoDent Solidex® Customized Abutment and Abutment Screw**	**Reference Predicate Device for claimed equivalence: Biomet 3i Encode Patient Specific Dental Abutment (K101608)**
Material	Abutment is Ti-6A1-4V Eli titanium alloy meets ASTM F-136 Standard and Screw is CP TI Gr4 meets ASTM F67 Standard	-Abutment and Screw: Comparable Titanium Alloy
Performance Characteristics	Allows the prosthesis to be cemented or screw retained to the abutment. The abutment screw is designed to secure the abutment to the endosseous implant.	Allows the prosthesis to be cemented or screw retained to the abutment. The abutment screw is designed to secure the abutment to the endosseous implant.
Indications for Use	The CreoDent Solidex® Customized Abutment is intended for use with an endosseous implant to support a prosthetic device in patients who are partially or completely edentulous. The device can be used for single or multiple-unit restorations. The prosthesis can be cemented or screw retained to the abutment. An abutment screw is used to secure the abutment to the endosseous implant. The CreoDent Solidex® Customized Abutment is compatible with the following: • Biomet 3i Osseotite Certain Dental Implants 3.25mm, 4mm, 5mm, 6mm	Encode Patient Specific Dental abutments made from Oral scans provided from Lava Chair Scanner and the 3M lava COS (2.0) software are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient. Encode Patient specific dental abutments are intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained.
Dimensions	Creodent Solidex Customized Abutment sizes	Biomet 3i Encode Abutment sizes for

and Angulations	for Biomet 3i Osseotite Certain 3.25mm, 4.0mm, 5.0mm and 6.0mm diameter implants. Angles not to exceed up to 20 degrees from the implant axis.	Biomet 3i Osseotite Certain 3.25mm, 4.0mm, 5.0mm, 6.0mm diameter implants. Angles not to exceed up to 30 degrees from the implant axis.

Non-clinical Testing Data: Static/Fatigue testing was conducted in accordance with ISO 14801:2007E Dentistry-Implants-Dynamic fatigue test for endosseous dental implants with the worst case scenario for the Solidex® Customized Abutment connection platform. Reverse engineering dimensional analysis using compatible implant fixtures and sterilization validation according to ISO 17665-1 was performed.These results demonstrated that the Solidex® customized Abutment have sufficient mechanical strength for their intended clinical application and are compatible with the Biomet 3i Osseotite Certain Dental implant system for which they are intended.

Substantial Equivalence discussion: The difference between the subject device and the reference predicate is the angulation. This difference is mitigated by fatigue testing, reverse engineering dimensional analysis.

Table #3 Legally marketed predicate device (Abutment) to which equivalence is claimed:

Technological Characteristics	**CreoDent Solidex® Customized Abutment and Abutment Screw**	**Reference Predicate Device for claimed equivalence: Straumann Cares Titanium Abutment (K082764)**
Material	Abutment is Ti-6A1-4V Eli titanium alloy meets ASTM F-136 Standard and Screw is CP TI Gr4 meets ASTM F67 Standard	-Abutment and Screw: Comparable Titanium
Performance Characteristics	Allows the prosthesis to be cemented or screw retained to the abutment. The abutment screw is designed to secure the abutment to the endosseous implant.	Allows the prosthesis to be cemented or screw retained to the abutment. The abutment screw is designed to secure the abutment to the endosseous implant.
Indications for Use	The CreoDent Solidex® Customized Abutment is intended for use with an endosseous implant to support a prosthetic device in patients who are partially or completely edentulous. The device can be used for single or multiple-unit restorations. The prosthesis can be cemented or screw retained to the abutment. An abutment screw is used to secure the abutment to the endosseous implant. The CreoDent Solidex® Customized Abutment is compatible with the following: • Straumann Bone Level implants 3.3mm, 4.1mm, 4.8mm	Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns or bridges. The Straumann WN Cares Titanium Abutment is indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration is cement retained.
Dimensions and	Solidex Abutment sizes for Straumann Bone Level implants 3.3mm, 4.1mm, 4.8mm	Straumann Cares Abutment sizes for Starumann Bone Level implants 3.3mm, 4.1mm, 4.8mm

Angulations	Angles not to exceed up to 20 degrees from the implant axis.	Angles not to exceed up to 30 degrees from the implant axis.

Non-clinical Testing Data: Static/Fatigue testing was conducted in accordance with ISO 14801:2007E Dentistry-Implants-Dynamic fatigue test for endosseous dental implants with the worst case scenario for the Solidex® Customized Abutment connection platform. Reverse engineering dimensional analysis using compatible implant fixtures and sterilization validation according to ISO 17665-1 was performed. These results demonstrated that the Solidex® customized Abutment have sufficient mechanical strength for their intended clinical application and are compatible with the Straumann Bone Level implant system for which they are intended.

Substantial Equivalence discussion: The difference between the subject device and the reference predicate is the angulation. This difference is mitigated by fatigue testing, reverse engineering dimensional analysis.

Table #3 Legally marketed predicate device (Implant) to which compatibility is claimed for the Solidex® Customized Abutment:

Compatible Device	Implant Diameters	Implant Lengths
Biomet 3i Osseotite Certain implants. (K063341)	3.25mm 3.25mm 3.25mm 3.25mm 3.25mm	8.5mm 10.0mm 11.5mm 13mm 15mm
Biomet 3i Osseotite Certain dental implants. (K063341)	4.0mm 4.0mm 4.0mm 4.0mm 4.0mm	8.5mm 10.0mm 11.5mm 13mm 15mm
Biomet 3i Osseotite Certain dental implants. (K063341)	5.0mm 5.0mm 5.0mm 5.0mm 5.0mm	8.5mm 10.0mm 11.5mm 13mm 15mm
Biomet 3i Osseotite Certain Dental Implants (K063341)	6.0mm	8.5mm 10.0mm 11.5mm 13mm 15mm

Table #4 Legally marketed predicate device (Implant) to which compatibility is claimed for the Solidex® Customized Abutment:

Compatible Device	Implant Diameters	Implant Lengths

Straumann Bone Level implants (K083550)	3.3mm 3.3mm 3.3mm 3.3mm	8.0mm 10.0mm 12mm 14mm
Straumann Bone Level implants (K121131)	4.1mm 4.1mm 4.1mm 4.1mm	8.0mm 10.0mm 12mm 14mm
Straumann Bone Level implants (K121131)	4.8mm 4.8mm 4.8mm 4.8mm	8.0mm 10.0mm 12mm 14mm